33. A drug delivery composition according to claim 24 wherein one half is coated with an insoluble polymer and the other half is enteric or colonic coated.

REMARKS

The present amendment and response is submitted in an earnest effort to advance this case to issue without delay. Claims 1-25, 28-31 are pending in this application and remain rejected. Applicants traverse each and every rejection.

Applicants have amended the application. Applicants have amended claim 1 to further define one embodiment of the Applicants' invention in an effort to advance prosecution. Applicants have added claims 32 and 33, which correspond to original claims 26 and 27. Applicants have also amended the specification by adding a paragraph. Sufficient support for such an amendment can be found in the claims filed in the original application. Applicants certify that that no new matter was added as required by 35 USC § 132. Applicants have amended claims 19-25, 28-31 to correctly read to a drug delivery composition as in claim 1.

Rejections under 35 U.S.C. §112

Claims 21, 24, 25 and 31 are rejected under 35 U.S.C. §112, first paragraph as containing subject matter not described in the specification. Applicants traverse these rejections. The specification must be complete enough to enable one of ordinary skill in the art to make and use the invention without undue experimentation. The specification need not describe the conventional nor disclose what the skilled already possess.

White Consolidated Industries, Inc. v. Vega Servo-Control, Inc., 214 USPQ 796, 823 (Mich. 1982). Applicants submit that the Application as amended enables one skilled in the art to make and use the invention without undue experimentation. Thus, the rejections are obviated and withdrawal is appropriate.

The Action rejects claims 1-25 and 28-31 under § 112, paragraph 1 and alleges that the amendment changing the coating to a single aqueous coating represents a departure from the specification and the claims. Applicants traverse this rejection. Applicants certify sufficient disclosure may be found throughout the specification as originally filed. In particular, Applicants point out that the Examples use a single aqueous coating and as such provide more than sufficient support. Applicants submit that withdrawal of this rejection is appropriate.

The Action rejects claims 21, 22, 25 and 28 under § 112, 2nd paragraph for being inconsistent with a single aqueous coating. Applicants traverse this rejection. Applicants submit that adequate support for these claims may be found in the specification as amended and these claims are not inconsistent with a single aqueous coating. Additionally, Applicants amended claims 19-25, 28-31 to claim a drug delivery composition. Applicants respectfully request withdrawal of all of the rejections under 35 U.S.C. §112.

Rejections under 35 U.S.C. §103

The Action rejects claims 1-25, 28-31 under 35 USC § 103 as being unpatentable over Hatano, in view of Watts and further in view of Tanida and Paulos. Applicants traverse these rejections.

By way of review, one embodiment of the present invention is directed to a drug delivery composition comprising a HPMC capsule which may contain a drug, wherein the capsule may have a single aqueous coating such that a drug will be released from the capsule not in the stomach but in either the small intestine or the colon.

Claims 1-24 and 28-31 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hatano et al as applied to claims 1-10, 14-16, 19-20 and 28-30 and further in view of Watts, Tanida et al and Paulos. The rejection of these claims is respectfully traversed on the grounds that the Examiner has failed to demonstrate a *prima facie* case of obviousness.

Applicants submit that Hatano discloses that multiple coatings must be used with its drug delivery composition. In particular, the drug delivery composition in Hatano requires multiple coatings: (1) a polymer film soluble at low pH and (2) an enteric coating film. (Hatano p. 3, lines7-10; p. 9, lines 3-7.) Additionally, Hatano discloses that non-aqueous based coatings are used to coat a capsule. (see p. 13, lines 30-p. 16, line 27).

The Office Action alleges that Watts discloses the use of a redox sensitive material in the coating of the HPMC capsule. The mechanical strength of the capsules in Watts are weak and the capsule walls may be reactive with the medicament ingredients as a consequence of the ionic nature of the material. Additionally, the Watts' capsules do not have the same flexibility of HPMC capsules and require specially designed equipment, e.g. capsule manufacturing and filing and peeling machine. Due to the differences in the capsules used in Watts, it would not have been obvious to combine it with the capsules used in Hatano to arrive at the Applicants' invention.

Further, Applicants submit that the combined teachings of Hatano and Watts when taken for their entirety do not teach or suggest the Applicants' invention. Rather, they teach away since Hatano suggests that two coatings must be used. Applicants' invention surprisingly uses only one coating. The Examiner appears to pick and choose certain parts of the references and excludes certain necessary parts of the references. It is impermissible within the framework of 35 USC § 103 to pick and choose from any one reference only so much of it as will support a given position to the exclusion of the other parts necessary to full appreciation of what such reference fairly suggests to one skilled in the art. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.* 796 F2d. 443, 230 USPQ 416 (Fed. Cir. 1986). Applicants submit that Hatano's necessary two coating system cannot be excluded and respectfully request withdrawal of the rejection is warranted.

The Action combines Hatano with Paolos, Watts and Tanida to suggest that the Applicants' invention as a whole would have been *prima facie* obvious. It is a well settled principle that to establish a *prima facie* case of obviousness of a claimed invention under 35 U.S.C. §103, all the claim limitations must be taught or suggested by the prior art. MPEP 2143.03, *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Applicants submit that the deficiencies in the individual references are not remedied by their combination. Thus, the cited references, when taken for the entirety of their teachings, cannot be considered to teach or suggest the Applicants invention. Thus, the rejections of the claims based on the combination of the cited references is inappropriate and withdrawal of the rejections and reconsideration is respectfully requested.

In view of the present Amendment and Response, Applicants submit that the Application is in condition for allowance and favorable reconsideration is therefore respectfully requested.

Should the Examiner have any questions or comments concerning the above, the Examiner is respectfully invited to contact the undersigned attorney at the number listed below.

Respectfully submitted,

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Dated: September 26, 2002

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VERSION OF AMENDED CLAIMS WITH MARKINGS

TO SHOW CHANGES MADE

On page 4 between the paragraphs ending on line 14 and beginning on line 15, please insert the following paragraph:

In one embodiment of the present invention, the coating may be applied separately to empty HPMC capsule body and cap. In another embodiment the HPMC capsule body is coated with an insoluble polymer and the cap is enteric or colonic coated. In another embodiment, two equal HPMC capsule halves are filled with a caplet. In another embodiment of the present invention, a coating is applied separately to equal empty HPMC capsule halves. a stomach resistant coating may be applied to HPMC capsules having a sealing on the gap between capsule body and cap. In another embodiment, one half of the capsule is enteric coated and the other half is colonic coated. Alternatively, one half of the capsule may be coated with an insoluble polymer and the other half with an enteric or colonic coating. In another embodiment, a stomach resistant coating is applied to HPMC capsules having a first coating of a water soluble polyvinyl alcohol. The HPMC capsule may be coated with a film which is non-dissolving at pH < 3 to 4 and dissolving at pH>5.5. The HPMC content of the capsule shell may be in the range of from 10 to 90% by weight.

1. (Twice Amended) A drug delivery composition comprising a HPMC capsule capable of containing the drug, wherein the HPMC capsule is provided with a single aqueous coating such that the drug is not released from the capsule in the stomach.

19. (Amended) A drug delivery composition [system] according to claim 2 wherein the drug is one which is effective in the small intestine.

20. (Amended) A drug delivery composition [system] according to claim 1 wherein the drug is one which acts locally in the colon.

21. (Amended) A drug delivery composition [system] according to claim 1 wherein the coating is applied separately to empty HPMC capsule body and cap.

22. (Amended) A drug delivery composition [system] according to claim 21 wherein the HPMC capsule body is coated with an insoluble polymer and the cap is enteric or colonic coated.

23. (Amended) A drug delivery composition [system] according to claim 22 wherein the water insoluble polymer is ethyl cellulose.

24. (Amended) A drug delivery composition [system] according to claim 1 wherein two equal HPMC capsule halves are filled with a caplet.

25. (Amended) A drug delivery composition [system] according to claim 24 wherein the coating is applied separately to equal empty HPMC capsule halves.

28. (Amended) A drug delivery composition [system] according to claim 1 wherein the stomach resistant coating is applied to HPMC capsules having a first coating of a water soluble polyvinyl alcohol.

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29. (Amended) A drug delivery composition [system] according to claim 1 wherein the HPMC capsule is coated with a film which is non-dissolving at pH < 3 to 4 and dissolving at pH>5.5.

30. (Amended) A drug delivery composition [system] according to claim 1 wherein the HPMC content of the capsule shell is in the range of from 10 to 90% by weight.

31. (Amended) A drug delivery composition [system] according to claim 1 wherein stomach resistant coating is applied to HPMC capsules having a sealing on the gap between capsule body and cap.

32. A drug delivery composition according to claim 24 wherein one half is enteric coated and the other half is colonic coated.

33. A drug delivery composition according to claim 24 wherein one half is coated with an insoluble polymer and the other half is enteric or colonic coated.